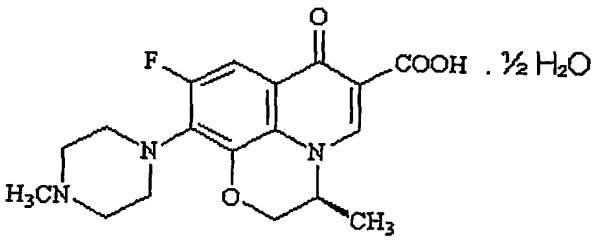
We claim:

1. A process for the preparation of pure (S)-9-fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-di][1,4]-benzoxazine-6-carbxoylic acid hemihydrate (levofloxacin hemihydrate) of Formula I,



FORMULA I

the process comprising obtaining a solution of crude levofloxacin in one or more organic solvents; removing the solvent; maintaining a moisture content of reaction mass from about 0.5%w/w to about 1.5%w/w; and isolating the pure levofloxacin hemihydrate.

2. The process of claim 1, wherein the solution of crude levofloxacin is obtained by heating the solvent.

3. The process of claim 2, wherein the heating temperature ranges from about 30 °C to about 100°C.

4. The process of claim 3, wherein the heating temperature ranges from about 40 °C to about 60°C.

5. The process of claim 1, wherein the organic solvent comprises one or more of chlorinated hydrocarbon, hydrocarbon, ester, or mixtures thereof.

6. The process of claim 5, wherein the chlorinated hydrocarbon comprises one or more of chloroform, dichloromethane, and 1,2-dichloroethane.

7. The process of claim 6, wherein the chlorinated hydrocarbon is dichloromethane.

8. The process of claim 5, wherein the hydrocarbon comprises one or more of hexane, cyclohexanes, and toluene.

9. The process of claim 5, wherein the ester comprises one or more of methyl acetate, and ethyl acetate.

10. The process of claim 9, wherein the ester is ethyl acetate.

11. The process of claim 1, wherein removing the solvent comprises one or more of distillation, and distillation under vacuum.

12. The process of claim 1, further comprising adding a base before removal of the organic solvent.

13. The process of claim 11, wherein the base is triethylamine.

14. The process of claim 1, wherein the moisture content of the reaction mass is maintained by adding water.

15. The process of claim 1, wherein isolating the pure levofloxacin hemihydrate comprises one or more of filtration, filtration under vacuum, decantation, and centrifugation.

16. The process of claim 1, further comprising additional drying of the product obtained.

17. The process of claim 1, further comprising forming the product obtained into a finished dosage form.

18. A method of treating a patient in need of an antimicrobial therapy, the method comprising providing a dosage form to said patient that includes levofloxacin hemihydrate prepared by the process of claim 1.

19. Levofloxacin hemihydrate having a purity of more than 99.0% by HPLC.

20. Levofloxacin hemihydrate having a purity of more than 99.5% by HPLC.

21. Levofloxacin hemihydrate having a purity of more than 99.8% by HPLC.

22. Pure levofloxacin hemihydrate, which is essentially free of levofloxacin monohydrate.

23. The pure levofloxacin hemihydrate of claim 21, wherein the levofloxacin hemihydrate has the X-ray diffraction pattern of Figure 1.

24. A pharmaceutical composition comprising a therapeutically effective amount of pure levofloxacin hemihydrate; and one or more pharmaceutically acceptable carriers, excipients or diluents.

25. A method of treating a patient in need of an antimicrobial therapy, the method comprising providing a dosage form to said patient that includes pure levofloxacin hemihydrate.